UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,047	04/15/2004	Steven Odrich	2755.025US1	7403

94210 7590 08/25/2010

Pillsbury Winthrop Shaw Pittman LLP (QLT)
P.O. Box 10500
McLean, VA 22102

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
08/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,047	ODRICH ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-19,21-33 and 35-46* is/are pending in the application.

4a) Of the above claim(s) *13,16,18,19,23-28,32,35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,15,17,21,22,29-31,33,34 and 37-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed June 25, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 – 1st Paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 22 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This new matter and written description rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed December 28, 2009 and those set forth below.

Applicant traverses this rejection by specifically pointing to paragraphs 16 and 20 of the specification and indicate that in the context of the specification as a whole, paragraph 16 makes clear that the implant is configured to release the active agent for a time period of between 3-6 months, which is why a visit to the eye doctor would only be

needed once per 3-6 months. These arguments are unpersuasive. The only place in which the 3-6 month time frame is mentioned is paragraph 20 and that time frame is mentioned in relation to needed frequency of office visits. The purpose(s) of the office visit and the timing of those visits are not disclosed and could be to check on the condition of the patient to determine if continued treatment was necessary. In order for this to support the time frame, the doctor's visit would have to have been disclosed as replacement a drug releasing implant whose drug supply had just been exhausted. Without such a linkage between time frame of drug release and the time frame of doctor's office visits, the new matter rejection is maintained.

In regards to the written description rejection, Applicant does not describe what configurations of the surface would provide such a time frame of release so the written description rejection is also maintained.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 11, 15, 17, 21, 22, 30, 31, 34, 37 and 41 were rejected under 35 U.S.C. 102(b) as being anticipated by Ness (US 3,828,777). This rejection is

MAINTAINED for the reasons of record set forth in the Office Action mailed December 28, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Ness does not disclose, teach or suggest an ocular device that has an implant body the extends from a proximal end portion to a distal end portion configured for insertion through the lacrimal canaliculus when implanted as recited in claim 11 as the body is adapted for insertion and retention in the sac of the eye. This argument is unpersuasive. The implant body of Ness has both a proximal and distal end. Those are the physical elements which are required by the claim. Implantation location is a recitation of intended use for the implant and the dimensions and shape of the device are such that is capable of being implanted as claimed by Applicant, then it meets the claim.

Applicant also argues that Ness does not disclose, teach or suggest that the entire body of the ocular insert is saturated with active agent as the insert made of a microporous material that is permeable to the drug. This argument is unpersuasive. The particular embodiment described by the Examiner, shown in figures 4 and 4A, contains filled pores (col 8, ln 19 – 33). In order for the pores to be filled, the microporous materials of the insert body, which serves as both the drug reservoir source and rate release controlling material, must be saturated with active agent.

Applicant also argues that claim 22 is rejected as being anticipated but the Office Action later states that it would have been obvious to prepare a drug releasing implant with a 3-6 month drug release time frame. By the Office Action's own admission, claim 22 is clearly not anticipated. These arguments are unpersuasive. The Office Action

states (p 12, ¶ 3) that Ness does not explicitly describe a prolonged release period of 3 - 6 months. A rejection under 102/103 as has been made in the instant case for claim 22 is appropriate when the prior art product seems to identical except that the prior art is silent as to an inherent characteristic (MPEP 2112 III). The release period is an inherent feature of the implant and as set forth, the structure of the implant, which determines the release period, is the same in the instant claims and the prior art. The release time frame for a particular implant is an inherent characteristic. Regarding the 103 rejection, if the implant as described by Ness did not have such a time frame, it would have been obvious to optimize the time frame of release, as set forth on p 12, ¶ 4 of the December 28, 2009 Office Action.

6. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (US 3,949,750). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 22, 2008, June 9, 2009 and December 28, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that the active agent of Freeman is not necessarily disposed entirely throughout the porous or absorbent material of the implant body and not necessarily saturated with an active agent. The punctum plug of Freeman may be used as a vehicle for storing and delivering ophthalmic medication to the eye as the punctum plug prevents drainage and thus systemic absorption of the drug. Delivery of the drug to the canaliculus would result in systemic delivery of the drug. In view of the overall teachings of the Freeman, one of

ordinary skill would understand that the entire plug body is not and should not be saturated with drug in order to prevent such systemic absorption. Inherency cannot be established by probabilities or possibilities. These arguments are unpersuasive. An embodiment is disclosed by Freeman in which the punctum plug is entirely made of a medication-impregnable porous material to store and slowly dispense ophthalmic drugs to the eye as they are leached our by the lacrimal fluids (col 5, ln 8 – 14). When the device is impregnated with drug, the device will be saturated with drug. That other embodiments falling outside the claimed invention does not negate the teaching of a species that falls within the scope of the claims. Applicants are essentially arguing that the statement regarding enhanced therapeutic safety for glaucoma therapy preventing drainage and thus systemic absorption is a teaching away from the instantly claimed implant but for rejections made under 35 U.S.C. 102, such considerations are not germane. It is also noted that delivery of the active agent as recited in the instant claims is to one or both of an eye or nasolacrimal system, so delivery to only the eye and not the nasolacrimal system is sufficient to meet the delivery location limitation recited in the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 11, 15, 17, 21, 22, 30, 31, 34, 37 and 41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ness (US 3,828,777). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed December 28, 2009 and those set forth herein.

Applicants traverse this rejection on the grounds discussed above as not teaching all of the elements. As discussed in greater above, Ness does teach all of the claimed elements.

11. Claims 11, 14, 15, 17, 21, 22, 29 – 31, 33, 34, 37, 38, 40 – 42 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ness further in view of Cohan et al. (US 6,196,993). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed December 28, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds that neither reference discloses, teaches or suggests the limitations of claims 11 or 30. As discussed in greater detail above, Ness teaches all of the claimed elements and therefore the limitations of the instant claims are met.

12. Claims 11, 14, 15, 17, 21, 22, 29 – 31, 33, 34, and 37 – 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ness and Cohan et al. further in view of Robertson (US 2002/0193441). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed December 28, 2009 and those set forth herein.

Applicants argue that Robertson does not remedy the deficiencies of Ness and Cohan discussed above. This argument is unpersuasive. As discussed in greater detail above, Ness and Cohan are not deficient so Robertson is not required to cure those deficiencies.

13. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ness US (3,828,777) in view of Yanni et al. (WO 00/03705).

Figure 4 of Ness discloses an ocular insert according to Ness (col 8, ln 19 - 33). The device is comprised of a body of microporous drug release rate controlling matrix material (**40**) having drug (**41**) dispersed throughout. Part **41** functions as both the reservoir and the release rate controlling mechanism to continuously dispense a metered amount of drug to the eye and tissue over a prolonged period of time (col 8, ln 23 - 28). As can be seen in figure 2, the implant body is configured to seat at or near a lacrimal punctum when implanted to a distal portion configured for insertion through the lactimal punctum into a lacrimal canaliculus when implanted. The drug is a medicine and the antibiotics or sulfonamides (col 8, ln 56 – 67) read on medication for treatment of an eye.

Ness does not disclose olopatadine as a drug which can be delivered using the implant.

Yanni et al. discloses that 11-(3-dimethylaminopropylidene-6,11-dihydrodibenzyl[b,e]oxepin-2-acetic acid, also known as olopatadine, can treat or prevent ophthalmic neovascularization and non-allergic inflammatory disorders involving cytokine release from human ocular cells by administering an ophthalmic formulation of olopatadine (p 3, ln 3 – 8). It can be administered to the eye via an implant (p 4, ln 9).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the implant of Ness to administer olopatadine. The person of ordinary skill in the art would have been motivated to make those modifications and

reasonably would have expected success because Yanni et al. discloses that olopatadine can be administered to the eye via implant for the treatment of ophthalmic neovascularization and non-allergic inflammatory disorders involving cytokine release. The materials that make up the implant will provide sustain release of the active agent (e.g., olopatadine) to tissue at or near one or both of any eye or a nasolacrimal system.

14. Claims 11, 15, 16, 21, 22, 29 – 31, 33 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Bhushan (US 2004/0137068). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed October 22, 2008, June 9, 2009 and December 28, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds that Bhushan does not remedy the deficiencies of Freeman discussed above. This argument is unpersuasive. As discussed in greater detail above, Freeman is not deficient so Bhushan is not required to cure those deficiencies.

15. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34, 37, 38, 40 – 42 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman further in view of Cohan et al. (US 6,196,993). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed June 9, 2009 and December 29, 2009 and those set forth herein.

Applicant traverses this rejection on the grounds that neither reference discloses, teaches or suggests the limitations of claims 11 or 30. As discussed in greater detail above, Freeman teaches all of the claimed elements and therefore the limitations of the instant claims are met.

16. Claims 11, 15, 17, 21, 22, 29 – 31, 33, 34 and 37 – 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman and Cohan et al. further in view of Robertson et al. (US 2002/0193441). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed December 28, 2009 and those set forth herein.

Applicants argue that Robertson does not remedy the deficiencies of Freeman and Cohan discussed above. This argument is unpersuasive. As discussed in greater detail above, Freeman and Cohan are not deficient so Robertson is not required to cure those deficiencies.

17. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman (US 3,949,750) in view of Yanni et al. (WO 00/03705).

Freeman discloses a punctal plug by using the plug as a means to prevent drainage of lacrimal fluid from the eye or as a carrier vehicle for storing and delivering medication to eye (col 1, ln 8 – 14). The plug is impregnated with or otherwise acts as a carrier material for an ophthalmic medication (abstract). As can be seen in figures, particularly figures 2A and 2B, the plug can have a head region (part 28 or 28') and a

lower portion (part 22 or 22') which is an inner stopper structure as recited in claim 33. In certain embodiments, the plugs (part 20 or 20'), or particularly the head portion, can be made of a porous material or otherwise configured to store and slowly dispense ophthalmic drugs to the eye as they are leached out by the lacrimal fluids (col 5, ln 8 – 14 and claim 4). Thus, Freeman discloses a punctual plug comprised entirely of porous material with medication-discharge from an exterior surface portion of the plug body and provides a sustained release of the active ingredient from the plug. The implant body comprised of porous or absorbent material has the active agent disposed entirely throughout.

Freeman does not disclose olopatadine as an active agent that can be delivered using the punctal plug.

Yanni et a. discloses that 11-(3-dimethylaminopropylidene-6,11-dihydrodibenzyl[b,e]oxepin-2-acetic acid, also known as olopatadine, can treat or prevent ophthalmic neovascularization and non-allergic inflammatory disorders involving cytokine release from human ocular cells by administering an ophthalmic formulation of olopatadine (p 3, ln 3 – 8). It can be administered to the eye via an implant (p 4, ln 9).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the implant of Freeman to administer olopatadine. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Yanni et al. discloses that olopatadine can be administered to the eye via implant for the treatment of ophthalmic neovascularization and non-allergic inflammatory disorders involving

cytokine release and would provide prolonged release to the eye from the implant with without daily application by the patient.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Nissa M Westerberg/
Examiner, Art Unit 1618